PFIH Feasibility/Implementation Study

A Report

prepared

for

The Prince's Foundation

for

Integrated Health

By

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PFIH Feasibility/Implementation Study

Executive Summary

a) This report has been undertaken at the request of the Prince's Foundation for Integrated Health (PFIH). It is designed to explore the feasibility and implementation issues surrounding the establishment of a federal system of regulation for those complementary therapies which are currently voluntarily regulated, who wish to support a federal structure and who meet the criteria set out in the recommendation in this report.

b) The report has drawn on a number of sources relating to professional regulation, from a variety of disciplines. It also considers proposed changes in current regulatory approaches, specifically those put forward in the two recent reports on non-medical and medical regulation by Andrew Foster and Sir Liam Donaldson respectively, which are out for consultation until November 2006.

c) The report identifies the key issues which need to be taken into account when considering the establishment of a federal system.

d) Due to time constraints, this study was undertaken concurrently with the consultation on the proposals for the federal approach, undertaken by PFIH. This was done on the understanding that if the consultation did not support the proposal for a federal approach, the work on implementation would proceed no further.

e) In the event, the consultation confirmed broad support for the principle of a federal approach, albeit with a number of detailed issues of concern to be addressed. This report has therefore taken those considerations into account in its proposals for the way forward.

f) The report concludes with a number of recommendations to The Prince's Foundation for Integrated Health.

Introduction

1. In April 2006, The Prince's Foundation for Integrated Health (PFIH) commissioned a feasibility/implementation study to explore issues surrounding the establishment of a federal approach for those complementary therapies which are currently voluntarily regulated and are not seeking statutory regulation. The study has been designed to run in parallel to the formal consultation being undertaken by PFIH on 'Exploring a Federal Approach to Voluntary Self Regulation of Complementary Healthcare' (PFIH 2006). This report was prepared in order to inform PFIH and to consider the steps that need to be taken next in progressing the federal approach to regulation, should that be the desired outcome of the consultation process.

Background

2. The proposal for a federal approach to the regulation of complementary health care originally came from a report commissioned in 2005 by PFIH from Professor Julie Stone, Visiting Professor of Ethics, School of Health and Social Care, University of Lincoln (Stone Report 2005). In that report three options were explored – maintaining the status quo, establishing a range of single therapy regulatory bodies or the establishment of a federal structure for those complementary therapies that were not pursuing statutory regulation. The report concluded that the federal approach had a significant number of advantages for the professions concerned, including:

- high levels of public protection
- achieving wider legitimacy within the regulatory field
- enabling professions to move to statutory regulation should this be desired by them or demanded of them
- provision of a framework for research which could further improve credibility and improve patient care
- being at the forefront of regulatory excellence by establishing a new model.

3. PFIH agreed to examine this model in more detail and subsequently held a range of events designed to explore further the implications of such an approach. The events included a wide range of participants, including:

- practitioners from a wide variety of professions
- representatives from various professional associations and emerging regulatory bodies within complementary therapies
- representatives from the statutory regulatory fields
- the independent Chairs of the various groups currently working towards voluntary regulation
- consumers/patient groups
- independent experts within the field of professional regulation
- Government departments
- Higher and professional education

4. The support from these events was such that it was agreed to consider the proposal for the establishment of a federal approach for voluntary self regulation for complementary therapies in more detail. A further report was prepared which has formed the basis for the formal consultation on the PFIH proposals which took place from May - July 2006. The

conclusions from the consultation have informed the final recommendations made in this paper.

Which professions?

5. PFIH currently has eleven groups within its existing regulation programme. It should be noted that their inclusion in the current programme which was designed to support the establishment of single uni-professional regulatory bodies, does not indicate whether or not they would be in favour of a federal approach. It is recognized that any proposals for the future would need to be designed to incorporate a variety of professional groups, which may or may not include those below:

Group	Estimated practitioners[1]	No of member orgs
Alexander Technique	1000	4
Aromatherapy	6930	15
Bowen technique	760	3
Cranial therapy	750	6
Homeopathy	3000	9
Massage therapy	9170	6
Naturopathy	820	13
Nutritional therapy	1500	3
Reflexology	26000	10
Yoga therapy	350	10
Reiki	7000	12

Rationale for change

6. The professional groups described above range considerably in terms of their current standards, professional education and requirements for registration. As a general rule they are characterized by a plurality of approaches – often based on a 'guru' approach to professional education, with a range of professional bodies and associated registers and with a wide range of standards of education and practice. This approach frequently results in several professional associations and a number of practitioner registers within the same profession, making it potentially difficult for the consumer to gain accurate and objective information.

7. Substantial work is currently being undertaken within each profession to rationalize and improve standards and significant progress has been made over the past few years. However, there is a danger that much work is being duplicated and also real concern that effective regulatory systems will simply be too expensive for many of the professions concerned to maintain on a uni- professional basis, especially where the numbers concerned are comparatively small.

Professional regulation and professional associations/organisations

8. *The regulation of the non-medical healthcare professions A Review by the Department of Health'* (July 2006) defines regulation as 'the set of systems and activities intended to ensure that healthcare practitioners have the necessary knowledge, skills, attitudes and

[1] Figures as of May 2005

behaviours to provide healthcare safely. This encompasses activity undertaken by individual professionals, teams, employers, regulatory bodies and other organisations.' It goes on to re-iterate the core elements of regulation as quoted in the Health Act (1999):

a) keeping the register of members admitted to practice
b) determining standards of education and training for admission to practice
c) giving advice about standards of conduct and performance
d) administering procedures (including making rules) relating to misconduct, unfitness to practise and similar matters' (Health Act 1999).

9. Whilst the definitions quoted above refer to the regulation of statutory regulated professions, there is a lot of shared learning available for those professions which are regulated voluntarily, as these functions are equally applicable to both sectors.

10. The prime purpose of professional regulation is public protection. Whilst there will also be considerable benefits for the professionals in the production of visible standards, the professionals themselves are not the main focus of regulation – the focus lies with the consumer. This principle must lie at the heart of any proposed regulatory system.

11. Concurrently, other systems need to be in place to support the individual professional and this is the key focus of the essential work of the professional associations/organisations. This differentiation is an important one as the regulatory picture evolves, especially as both roles – that of maintaining a register and that of supporting the individual professional – have traditionally and until recently been undertaken by many of the existing bodies who currently run professional registers within complementary healthcare. In separating the roles, it is important to recognise the continued inter-dependence of both sets of activities.

12. Broadly the roles can be summarised as follows:

Key Roles of the regulator
Main focus - public protection
To establish and maintain*:*

- a register of qualified professionals
- standards for:
  - entry to the register
  - maintaining registration
  - removal from the register – temporarily or permanently
- standards for professional education, including CPD
- standards for accreditation of courses leading to professional qualifications
- a Code of Professional Conduct/Ethics
- a Fitness to Practise system

Key Roles of the professional associations/organisations
Main role- support for the individual professional

- to support individual professionals in a variety of ways

- to promote the profession and professional practice
- to provide CPD activities
- to facilitate/provide professional indemnity insurance
- to raise professional standards
- to provide the supporting services of a trade union
- representation in cases of allegations of misconduct

Regulatory Impact Assessment

13. In the preparation of this paper, attention has been paid to the guidance given by The Cabinet Office on Regulatory Impact Assessment. This is a process designed to help deliver policy objectives successfully. Although primarily designed for policies which need Government intervention, it does provide some useful pointers for voluntary regulation. It provides a framework for analysis of the likely impact of a policy change and the range of options for implementing it.

14. The approach is appropriate for voluntary regulation as it looks at the full range of potential impacts - economic, social and environmental and where the impact may fall – business, the public sector, the voluntary sector or other groups. It supports the Government's aim of only regulating when necessary and if necessary, to do so in a way that is proportionate to the risk being addressed – deregulating and simplifying wherever possible. It asks those devising policy to make sure they consider their rationale for action; associated risks; costs and benefits and the next steps and these issues are variously addressed throughout this report.

Generic principles of regulation

15. Any good regulatory system needs to adhere to certain principles and a number have been identified by various players. The Better Regulation Task Force (BRTF) [now The Better Regulation Commission (BRC)] is an independent advisory body which was set up by the Government in 1997. Its role is to advise the Government on action to ensure that regulation and its enforcement accord with the five principles which it has identified, which are that systems should be:

Proportionate: regulators should only intervene when necessary. Remedies should be appropriate to the risks posed, and costs identified and minimised.

Accountable: regulators must be able to justify decisions, and be subject to public scrutiny.

Consistent: Government rules and standards must be joined up and implemented fairly.

Transparent: regulators should be open, and keep regulations simple and user friendly.

Targeted: regulation should be focussed on the problem, and minimise side effects.

16. The review undertaken by Philip Hampton *Hampton review* (2004) looking at UK regulation in business, further proposes entrenching the principle of risk assessment

throughout the regulatory system so that the burden of enforcement falls most heavily on high risk business and less on those with best records of compliance – ie putting comprehensive risk assessment into a streamlined structure.

17. Other professional commentators on regulation have included additional principles such as:

- *purposefulness* - regulation should always be directed towards a specific purpose
- *relevance* - regulation should be designed to achieve its stated purpose
- *definition* - regulatory standards should be based upon clear definitions of professional scope and accountability
- *multiple interests and responsibilities* - regulatory systems should recognise and incorporate the legitimate roles and responsibilities of interested parties, the public, the profession, and its members, government, employers and other professions - in various aspects of standard setting and administration
- *representational balance* - the design of the regulatory system should acknowledge and appropriately balance interdependent interests
- *professional optimacy* - regulatory systems should provide and be limited to those controls and restrictions necessary to achieve their objectives
- *flexibility* - standards and processes of regulation should be sufficiently broad and flexible to achieve their objective and at the same time permit freedom for innovation, growth and change
- *efficiency and congruence* - regulatory systems should operate in the most efficient manner, ensuring coherence and coordination among their parts
- *universality* - regulatory systems should promote universal standards of performance and foster professional identity and mobility to the fullest extent compatible with local need and circumstances
- *fairness* - processes should provide honest and just treatment for those parties regulated
- *inter-professional equality and compatibility* - in standards and processes, regulatory systems should recognise the equality and interdependence of professions offering essential services. (ICN 1998)

Key players

18. Any proposals for change in the regulation of complementary therapies need to identify clearly the key players who have an interest in this activity. They fall broadly into two groups: a) those with a direct and immediate interest and b) those with a more indirect, but nonetheless significant interest.

Group a)
Patients/potential patients
Public/consumers
Complementary therapy professional organisations/associations
Individual practitioners
Groups working on Complementary Therapy regulation
PFIH

Education providers within professions – public and private

Group b)
Government Departments
NHS bodies – acute trusts; PCTs
Private healthcare providers
Insurance companies
Higher Education providers
Statutory health-related regulatory bodies
Professional Bodies/Royal Colleges
Health Related Charities
Skills for Health
Learning and Skills Councils
European bodies

Patient and public involvement (PPI)
Generic views

19. '*Healthcare professionals on the ground have daily contact with patients and a strong sense of what patients want. Yet society is changing and involvement by proxy is no longer seen to be enough. The public are no longer prepared to be passive, trusting and grateful recipients of what is made available. The public are ready to challenge, prepared to question and come to expect that services will be responsive to their needs*.' (The Kennedy Report 2001)

20. The issue of patient and public involvement deserves specific attention for a number of reasons. The current interest in and popularity of complementary therapies has arisen because of public demand. There is greater awareness of the range of therapeutic interventions that are available and more demand for them by a public that judges by results and wishes to be involved in decision making with regard to its own health.

21. Some recent work has been undertaken on why individuals wish to get involved with regulatory bodies (PPIG 2006) and this should be taken into account when planning any new structure. The following issues were identified:

- to improve services for themselves and those who come after them
- to influence the agenda
- to ensure that priority issues are addressed
- to ensure that regulation in the future is appropriate for people like them
- altruism – wanting to give something back to the public as a whole, or to services from which they have derived benefit
- sharing their knowledge, skills and experience from other related areas of work to the benefit of others
- having a right to involvement as key stakeholders.

22. On what basis should patient and public involvement be based?

- the public and patients should have access to relevant information

- there must be honesty about the scope of public and patients' involvement, since some decisions cannot be made by the public
- there must be transparency and openness to the procedures for involving public and patients
- the public and patients should have access to training and funding to allow them to participate fully
- the public should be represented by a wide range of individuals and groups and not only by particular patient groups
- the mechanisms for involvement should be evaluated for their effectiveness.

Specific views

23. The views of a wide range of individuals, who are not involved in the regulation of complementary healthcare, have been sought in the preparation of this report, as legitimate representatives of the public and potential consumers. Their comments have been most helpful. The overwhelming view appears to be that any federal structure - in order to ensure public confidence - should, as a minimum:

- have some form of minimum appropriate education and training for the profession in question ie to be 'properly qualified'
- have a code of conduct
- have a complaints/fitness to practise mechanism
- ensure that its practitioners are adequately insured.

24. In addition, the following additional standards were also variously mentioned:

- provision of information about the therapy concerned
- information on the evidence base for the therapy
- explicit educational/professional standards accredited by a reputable academic body
- requirements for continuing professional development (CPD)
- statements of requirements of conduct (not guidance)
- child protection checks.

These views need to be taken into account in terms of the decisions to be made.

Recent reports on medical and non medical regulation

25. Whilst this study was being undertaken, two much anticipated reports were published in July 2006 by the Department of Health in England, which are likely to have significant implications for regulation: '*The regulation of the non-medical healthcare professions A Review by the Department of Health'* (July 2006) by Andrew Foster, Director of Workforce, DoH (the 'Foster Review') and ' *Good doctors, safer patients. Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients. A report by the Chief Medical Officer*. (July 2006) by Sir Liam Donaldson, CMO.

26. Although both reports deal with professions which are statutorily regulated, there are a number of messages for all healthcare regulation. The key points of relevance to this work appear to be as follows:

27. *The regulation of the non-medical healthcare professions*

- regulation of the professions needs to be coordinated with the regulation of the health services – need for an integrated and consistent framework with greater clarification of the role of employers, where applicable
- need for consistency of standards across regulators
- re-validation (formative and summative) is necessary for all professionals - standards for *maintenance* of registration are very important but this needs to be developed in a risk-based way
- Health Care Commission to approve employers who can deliver re-validation processes
- regulation generally to be proportionate and risk-based
- single source of advice for those who want to complain about registrants
- fitness to practise processes should work to common standards (with the possibility of a single outsourced adjudication system being scoped)
- no new regulators – any new professions to go to an existing body
- concept of 'lead regulator' for those on more than one register
- some or all of elected Council members should be replaced by appointments
- balance of lay/professional members need to be re-scrutinized (? Professional majority of 1; ? lay majority of 1)
- professional bodies needed to (continue to) provide leadership and set standards and work with regulators
- separation of regulatory and professional representative functions for pharmacy to bring it in line with other professions

28. *'Good doctors, safer patients'*

This report deals, in the main, with the regulation of doctors and the role of the GMC but makes the following more general points of relevance about regulation:

- the international trend is to move away from a regulator which houses all functions 'under one roof' with regard to complaints (ie the same body being recipient, processor, investigator, judge and jury)
- the standard of proof for factual allegations of misconduct should be determined using the civil standard rather than the current criminal standard used by the GMC
- there should be a separate and independent tribunal to adjudicate on fitness to practise cases
- a clear and unambiguous set of standards should be created for generic medical practice
- English language proficiency and clinical knowledge should be formally assessed through a standardised national examination for **all** initial registrants
- Medical students should be registered with the GMC
- Re-validation and re-licensing must have specific objective standards attached

- Information on the GMC register should be freely available: registration status; date of expiry of license to practise; specialist certification; any interim or substantive restrictions on practice in force

29. The proposals in these two reports are currently out for consultation until November 2006. However, there are a number of implications for professional regulation and it is important that the key messages are picked up in the work on a federal approach for complementary healthcare.

30. The key themes are:

- patient safety at the heart of regulation
- the need for consistency of standards across all regulators
- re-validation being necessary for all professionals (ie standards for maintaining registration)
- a single source of advice for those who want to complain about registrants (including fitness to practise processes which should work to common standards)
- no new regulators;
- balance of Councils must change significantly - more lay members
- professional bodies must continue to offer leadership and work with regulators.

PEST and SWOT analysis

31. In order to undertake a 360 degree analysis of the proposals for a federal approach to regulation two analyses have been undertaken - a PEST analysis and a SWOT analysis - as set out in Figs 1 and 2 below.

Fig 1 **PEST Analysis**

POLITICAL

1. Supports moves to fewer rather than more regulators
2. Powerful voice of many professions
3. Possibility of further DH funding
4. 'Foster' & 'Donaldson' – fit with current political thinking
5. 5.Strong patient voice
6. Possibly paves way to statutory regulation, if professions wished to go that route in the future
7. Strong voice in relation to EU or International discussions
8. 4 country approach – proposal must fit all 4 countries of UK
9. Increased likelihood of endorsement by
   - Government
   - Statutory regulators
   - Insurers
   - Patient groups

ECONOMIC

1. Reduce expensive duplication of activity, resources
2. Maximize economies of scale
3. Need for start-up costs and staged development to ensure financial viability
4. One source of patient/consumer information to save time and effort

SOCIOLOGICAL

1. Separation of regulation and professional body functions
2. Flexible approach to accreditation
3. 'Kite marking' gives quality control, in understandable way for public
4. Legitimization through media / single source of information
5. Multidisciplinary roles can be accommodated more easily
6. Promotion and visibility of therapies

TECHNOLOGICAL

1. Register / IT/database/website
   - Sharing facilities
   - Research
   - Communications

Fig 2 SWOT Analysis

STRENGTHS

1. Increase in public protection
2. Consistency in regulatory issues
3. Standardisation
4. Single point of contact for the public
5. Political power of larger group
6. Use of limited expertise
7. Sharing resources (? Economies of scale)
8. Innovative model
9. Multi-therapy advantage for those with more than one profession – register under 'one roof'
10. Professional resource
    - sharing and learning
11. Synergy/collective energy
12. Professionalisation of therapies
13. Financial flexibility and sustainability
14. Great capacity for 'branding'
15. Affordable fees
16. Capacity to set benchmarks for acceptable practice
17. CRB checks for all

WEAKNESSES

1. Communication within and between therapies very variable
2. Voluntary system
3. No protection of title
4. Perceived loss of professional status
5. Lack of identified resources e.g. start up costs
6. Lack of leadership within the professions concerned
7. Considerable disagreement within therapies especially on styles of practice
8. Professional tendency to fragment in the face of disagreement
9. Constraints of part time practice may reduce involvement
10. Professions at very different stages, conceptually and practically
11. Marked lack of understanding amongst practitioners of current situation, let alone future proposals

OPPORTUNITIES

1. More powerful voice for CAM
2. A 'CAM' approach to regulation
3. Increase in the amount of regulatory expertise
4. May be cheaper
5. Increase in public confidence
6. Create opportunities for a research network
7. Rationalisation of professional organisations
8. Health care insurance - possible reductions
9. Possible increase in NHS work
10. Possibly pave way to statutory regulation, if desired
11. Influence CAM in other countries
12. Income generation
13. Opportunity to influence government bodies

THREATS

1. No DH money/support
2. No FIH money/support/staff
3. No buy-in from the profession
4. Some do/don't – partial buy-in
5. Professional bribery - conditional buy-in
6. Number of and relationships between associations already difficult in places
7. Professional associations – reluctance to relinquish tasks
8. Ability / inability to cope with expansion
9. Transitional arrangements too complicated
10. Lack of trust at a variety of levels
11. Misinformation – accidental and deliberate
12. Requires working across and well as within professions - very challenging
13. Hard choices to be made about eligibility
14. Loss of key people within regulation with loss of continuity & expertise

Professional concerns to be addressed

32. Prior to the formal consultation, a number of concerns had been expressed by the existing bodies working on various aspects of regulation, which need to be addressed as part of any proposals for the future. They included:

- costs – will a federal structure be cheaper or more expensive – could be expensive to run
- will some practitioners be prepared to pay higher fees
- loss of professional identity within a larger body
- need to maintain distinct professional autonomy
- professions must be responsible for their own practice standards
- could bigger groups out-vote smaller ones?
- interference by the 'big' body
- should single profession regulation not precede a federal structure?
- how effective is the HPC model?
- is this a secret route to statutory regulation?
- is there a hidden agenda here?
- do the proposals recognize that most complementary therapists are self employed?
- federal structure is complementary and should try to synergise rather than equalize
- fear over loss of professional accreditation from professional associations
- transitional arrangements will be tricky
- new structure poses threat to professional organizations

Response to consultation

33. The analysis of the consultation responses was undertaken concurrently with the writing of this report, owing to unavoidable time constraints. However, sufficient information helpfully was made available to the author of this report, and the project Steering Group, to inform the recommendations.

34. Overall, **there is a clear mandate for the principle of a federal approach** to the regulation of complementary healthcare. The detail of the support for the proposals is to be found in the consultation analysis.

35. That said, it is also clear that there are a number of concerns about the detail of the proposals which need to be taken into account in taking the proposals forward and are therefore properly the business of this report. These include:

a) *Understanding* – The essential difference between public protection (as the business of the regulator) and professional status (as the business of the professional associations) appears not yet to have been grasped by a significant number of respondents. Without this understanding, some respondents have had some difficulty in

grasping what is being proposed, for example, some agree with a federal structure but wish to keep the registers with the professional associations.

b) *Timeframe* – appears to be too fast – there is a need for a lot more information and time to grasp ideas before completion

c) *Communication strategy* - Publicity/information – poor level of knowledge of existing situation which makes for lack of understanding of proposals for the future. There is a need for a substantial, well organized communications campaign for both the professionals concerned and for the public

d) *Professional associations* – will clearly need special consideration to reassure them that there is ample work for both regulator and professional associations in any future scenario

e) *Need for diversity of practice* - respondents wish to see the diversity of professional practice continue to flourish and not be constrained by regulation

f) *Cost* – The issue of cost per practitioner is clearly a very sensitive area – robust financial models will be needed once options are identified.

Establishing a federal model – issues for consideration

36. The first part of this report has explored in some detail the background and key issues for consideration with regard to the proposed federal structure for complementary therapies. This information has been supplemented by the results of the formal consultation undertaken by PFIH. It now remains to apply all these considerations to proposals for a possible way forward.

37. This report has taken as its basic stance that, provided the participants (ie professions) concerned are willing, any project is feasible. Clearly the detail of the actual proposals will need to be taken forward by any representative group established to progress the project (see Recommendations). It is only in this way that genuine ownership of the eventual form and function of the federal structure can be achieved. What follows is an attempt to identify the issues that will need to be considered and explored more fully**.**

38. It is important to remember that any proposals relating to a federal structure are designed to regulate the <u>practitioner</u> not the professional practice.

<u>Principles for a federal approach</u>

39. The system should

- have public protection as its main aim
- be developmental
- be ‘light touch’
- be designed to incorporate the valued work already undertaken by many of the regulatory groupings
- allow for the incorporation of new professions, provided they meet the requisite criteria

- involve adequate and effective public and patient involvement
- allow for a diversification of approaches to professional practice
- allow for proper representation of the different professions

40. Criteria for joining

Q. What criteria would be required for a profession to apply to join a federal structure?

- professional/therapeutic definition – what constitutes a therapy? Merely the voice of those involved or does it need something more? This, in itself, could be highly controversial
- evidence of the effectiveness of therapy – how does one judge its legitimacy ? does one need research evidence/ an evidence base?
- what is the role of research?
- need for number of practitioners – minimum/maximum
- minimum standards – for example
    - safety
    - competence
    - NOS
    - education – hours of study?
    - practice
    - registration
- professional register
- complaints and fitness to practise mechanisms

41. By way of comparison, the current criteria for entry to the HPC is that the profession has

- discrete area of activity
- defined body of knowledge
- evidence based practice
- one professional body representing most practitioners
- voluntary register
- defined entry routes to training
- independently assessed qualifications
- code of conduct applied to voluntary registrants
- disciplinary processes applied to voluntary registrants
- commitment to CPD

42. *Size of federal structure*

Q. How many professions are to be involved for the idea to be viable?

Should there be a minimum number of participant professions?

There must be an optimum minimum number of contributing bodies to make a federal approach both credible and viable financially. Best estimates would indicate that a minimum of 3/6 professions would be needed to establish a realistic structure. The more professions who join, the greater the economies of scale for the participant members.

There may also be an issue about the optimum number of individual practitioners that would make this approach viable.

Should there be a maximum number of participating professions?
HPC (the only federal structure currently in existence) currently has 13 participant professions and several others applying to join (8 that have gone through the HPC process and are awaiting new parts to the register; and a further 10 that are awaiting processing). No ceiling is likely to be put on to the number of professions seeking registration, providing they meet the criteria, although the implications of expansion on the composition of the Council itself are currently underway.

43. *Levels of assurance*
Q. Would it be practical to have different levels of assurance; for example:

Level 1 - minimum
Professional indemnity insurance
Complaints/fitness to practise mechanism available to call practitioners to account
Code of conduct
Criminal Records Bureau (CRB) checks

Level 2 - medium
Professional indemnity insurance
Complaints/fitness to practise mechanism
Code of conduct
Criminal Records Bureau (CRB) checks
Competency standards for professional practice for the therapy concerned eg NOS

Level 3 - maximum
Professional indemnity insurance
Complaints/fitness to practise mechanism
Code of conduct
Criminal Records Bureau (CRB) checks
Competency standards for professional practice for the therapy concerned eg NOS
Educational standards
Accreditation process

44. A 'graded' approach of this nature could have advantages in that it would ensure a developmental approach; would be a more inclusive model than one with high start-up standards and professional groups would be given goals to work towards for the benefit of their profession. However, the disadvantages would probably outweigh the advantages in that it could be confusing for the public and other healthcare practitioners. Minimum standards may be unacceptably low and it might need further consultation

Approaches to organisational structure
45. Whilst the consultation document described a relatively specific structure and function for the new body, the range of issues raised in the consultation means that

further exploration of other approaches should not be ruled out, in order to ensure that the consultation concerns are adequately addressed. In addition, the two reports on professional regulation referred to in Section 10 also have implications for the project in hand. What follows therefore is a discussion on the possible approaches which may be considered, in whole or in part.

46. Clearly it will be for the Working Group which will need to be established (see Recommendations) to take the discussions forward in detail. Elements of the approaches are not necessarily mutually exclusive and could be viewed as a progression, or staged approach, towards an ultimate outcome. There would appear to be 5 possible approaches for consideration and further exploration here:

Approach 1

47. A virtual body consisting of a loose alliance of interested parties who share information and standards but maintain their own professional autonomy, run their own registers and manage their own fitness to practice mechanisms.

Advantages

- no disruption of the existing situation, which could be seen as an advantage to some
- sharing of some policies and procedures, which may be capable of adaptation
- no actual or perceived dilution of professional power, which may be seen as an advantage to some
- some possible reductions in 're-inventing the wheel'

Disadvantages

- inadequate separation of regulatory and professional roles – continued blurring of roles
- actual duplication of activity
- no economies of scale
- public confusion continues
- variable professional standards continue
- so loose, it is barely a federal approach
- would not address the issue of those who wish to practise a number of different therapies

Executive support required

No change from existing structures

Accountability structure

Would remain with the existing organisations and would vary from profession to profession

Risk assessment

So light touch it does not meet the criteria for a regulatory system. Existing public and professional confusion would remain

Costs
Little change from current structure-each body would need to establish own standards, with associated costs

Financial sustainability
Unknown – likely to vary from profession to profession

Approach 2
48. A virtual body which maintains a joint register of practitioners and agrees a basic set of minimum standards for entry on to register – could be staffed variously by existing registering organisations, with some sort of shared 'loose' Council or body to agree minimum standards
Advantages

- minimum disruption of current position could be seen as an advantage to some
- shared register, reducing technology costs
- public confusion may be somewhat abated
- might help to address the issue of those who wish to practise a number of different disciplines

Disadvantages

- inadequate separation of regulatory and professional roles – continued blurring of roles
- could add to existing public confusion
- how would the 'body' be managed, given the number of potential players involved
- how would fitness to practise issues be dealt with – danger of varying standards if it stays with individual professions
- varying standards could continue to erode public trust and confidence

Executive support
Could be staffed by existing staff within 'partner' organisations but would probably need a dedicated person to co-ordinate activity; one person to act as Registrar (a challenging role)

Accountability structure
Would have to be handled very carefully, to ensure no confusion. Would need 'heads of agreement' amongst participating organisations, to ensure consistent standards. Organisations would elect members to central Council to agree standards for entry to register; maintenance on register and removal from register. Complaints could be dealt with by each participating body or centrally

Risk assessment
Would need very careful management to avoid public confusion and ensure consistent standards

Costs
Some sharing of significant costs eg fitness to practice

Financial sustainability
Unknown - would depend on success of venture

Approach 3

49. A body which shares premises and functions only. It would have some form of hard standing (ie a building/part of a building), sharing a suite of facilities eg reception, switch board, board room, committee rooms and associated support staff. All professional standards and registers would be maintained separately by each profession, as is currently the case, although ideally there would have to be a single register within each therapy for clarity. The single registers could be held as a single source on the same electronic data base.

Advantages

- considerable economic savings – no need for own premises/facilities
- one initial source of information for public for those therapies involved
- could act as a conduit to additional information from the professional associations themselves, and/or
- could be a single register

Disadvantages

- inadequate separation of regulatory and professional roles – continued blurring of roles
- could add to existing confusion
- variable professional standards would continue – for practice, education and conduct
- would not address the issue of those who wish to practise a number of different disciplines

Executive support
Receptionist/telephonist; administrator for booking of premises etc; domestic support staff (refreshments, cleaning etc)

Accountability structure
Accountability for all professional activity would remain with existing organisations. Standards would have to be agreed amongst participating organisations with regard to use of rooms; associated costs; support required etc

Risk assessment
Considerable advantage to the professions in terms of economies of scale of shared premises etc. Some public advantage in terms of one central point to access information but none in terms of consistency of professional standards

Costs
Cost and benefit analysis would need to be undertaken but would appear to have significant cost reduction in terms of shared technology (one shared register); fitness to practice mechanisms; accreditation; source of public information. However, could still prove proportionately expensive for the smaller therapies

Financial sustainability
Depending on number of practitioners who register, probably sustainable

Approach 4
50. A fully federated structure which shares standards, processes and premises. A body with hard standing; staff; a single register; an over-arching Council of Members plus Profession Specific Boards (PSBs). The Council would be representative of the professions engaged in the debate and responsible for broad policy decisions, for example, fitness to practise, umbrella education/accreditation standards and associated processes. The PSBs would have responsibility for professional practice definitions, detailed education standards, core curricula. This is the approach which is most similar to that proposed in the consultation document.
Advantages

- visible and acceptable standards
- one source of regulatory information
- one register (albeit divided into parts for the different professions)
- consistency of standards across professions
- professional standards remain profession specific
- easier to manage multi- therapy practitioner regulation (eg having a 'main' registration category and 'supplementary' registration category (ies)
- greater parity with other bodies eg statutory regulation
- economies of scale for technology; office space; staff
- like to command Government support
- could address the issue of those who wish to practise a number of different disciplines

Disadvantages

- could the various professions ever agree details - difficult enough within each profession
- could disadvantage current smaller grouping who have not progressed so far
- could disadvantage those groups who have already progressed the furthest in terms of time and resource already committed
- could still be more expensive than some bodies are anticipating
- actual/perceived loss of professional autonomy
- what happens to those groups who are not 'in the frame'?

Executive support
Full executive support would be needed – Chief Executive/Registrar; Professional Officer(s) (complaints, professional advice; accreditation/education etc); administrative support staff; other support staff

Accountability structure
Responsibility for strategic direction would lie with the Council (elected or appointed), headed by an appointed or elected Chair. Appropriate balance of lay/professional members. Some generic committees eg fitness to practice and Profession Specific Boards appointed/elected from within the professions concerned – responsible to Council. CEO/Registrar responsible for all operational issues and progressing and implementing Council's policies; servicing Committees and Boards; management of the organisations executive staff

Risk assessment
Probably the most effective model with greatest congruence with existing statutory regulatory bodies. Would need to maintain light touch and ensure no over-regulation, especially in relation to Fitness to Practise

Costs
As 3 above

Financial sustainability
As 3 above

Approach 5

51. A substantially different approach could be to have a much smaller Council consisting of 'generic' experts, in, for example, law, professional ethics, education, finance and regulation. This may better reflect a more appropriate approach for complementary therapies. Profession-specific expertise would be located within the professional 'Boards', who would apply the over-arching standards to their own professions. Education and practice standards would be dealt with by the Boards, within the broad parameters set by Council. Generic fitness to practise processes would be managed by a process agreed by the Council with agreed routes for ensuring profession specific expertise.

Advantages

- individual therapies would keep control of their own standards within broad parameters set by the Council
- may be more appropriate for light-touch regulation for complementary therapies
- more visible involvement of professionals in PSBs
- a single route for public information
- consistency of approach to standards, particularly fitness to practise standards
- single register
- likely to command Government support

- could address effectively the issue of those who wish to practise a number of different disciplines

Disadvantages

- a very different model – may take some getting used to
- currently, no other similar model in the UK
- cost implications unknown
- professions may resent not being represented on the Council

Executive support

A range of executive support would be needed with Chief Executive/Registrar and staff to manage business and support Profession Specific Boards

Risk Assessment

This model, which is used for healthcare professions in Ontario, may have much to recommend it, in terms of keeping professional 'control' of standards and the fact that it is substantially different from other statutory regulatory models in the UK. This could also be its biggest risk

Costs

Unknown

Financial sustainability

Unknown

Summary of the consideration of the various models

52. Each of the options above have been considered against the principles identified throughout this report and summarized as follows: any system must have public protection as its main aim; be developmental; be 'light-touch'; be designed to incorporate the valued work already undertaken by many of the regulatory groupings; allow for the incorporation of new professions, provided they meet the requisite criteria; involve adequate and effective public and patient involvement; allow for a diversification of approaches to professional practice; allow for proper representation of the different professions. Such consideration, together with consideration of the responses to the consultation document, clearly narrows the options down to Approaches 4 and 5, as described above.

Recommendations

53. On the basis of the information set out in this report, and having received agreement on the federal approach, the following recommendations are made.

<u>Recommendation 1</u>: Approaches 4 and 5 (as described in paragraph 50 and 51 of this report) should be explored further as possible models for a federal approach to complementary healthcare regulation.

Having considered the options above, in the light of the principles set out earlier in this report, together with the results of the consultation, it is recommended that Approaches 4 and 5 warrant further consideration and should form the basis of the on-going work of the Working Group (see Recommendation.4 below).

<u>Recommendation 2:</u> Each profession which wishes to continue further discussion on a federal approach to complementary healthcare regulation must meet the criteria set out below in order to engage further in the debate.

Given that this work is in pursuit of effective public protection, there should be a clear and explicit minimum set of criteria for those professions who wish to engage in debate on a federal structure. This is to ensure that, whilst being as developmental and inclusive as possible, certain standards must be in place initially to avoid subsequent disappointment amongst the professional group concerned, and to avoid public confusion.

In order to engage in the next stage of debate on the establishment of a federal approach to regulation, there are a number of criteria which must be met by participant members, as follows:

1. The profession must wish to participate in the establishment of a federal approach for complementary healthcare and must demonstrate its commitment to the concept
2. The profession must have the following standards already in place, or must have an agreed timeframe, *of not more than two years*, by which the standards will be achieved,
    i. profession specific National Occupational Standards
    ii. a code of conduct
    iii. a complaints/fitness to practise procedure
    iv. lay representation/input into their regulatory deliberations
    v. a requirement for practitioner professional indemnity insurance
    vi. explicit standards for current registration
    vii. an established and sustainable source of income
3. Each profession must identify a representative and an alternate who are acceptable to the profession as a whole. The profession must also have clearly identified pathways for ensuring intra-professional communication, so that it can be assured that information flows are effective, both to and from the Working Group.

<u>Recommendation 3:</u> PFIH should develop a framework which ensures pathways for continued engagement with those professions who do not meet the above criteria.

It is accepted that in setting criteria for continuing the debate, it will, by definition, mean that some professions will be unable to engage in the process at this time. It is hoped that by setting out clear criteria, aspirant professions will be able to see clearly what standards they are required to meet, in order to be part of the eventual federal structure. Further consideration will also need to be given to the position of those professional groups who wish to continue to work towards uni –professional regulatory bodies.

<u>Recommendation 4:</u> A working group should be established without delay to progress arrangements for a federal structure.

Having received broad agreement on the principle of establishing a federal approach for complementary therapies, it is for a working group of representatives of participant professions who must now take the proposals forward. (See Recommendation 5 for details). Funding for this initiative will need to be sought.

<u>Recommendation 5:</u> The Working Group should be as broadly representative as is commensurate with economy and efficiency.

Representation should consist, as a minimum, of:

a. One representative and a named alternate from each profession expressing an interest in establishing a federal structure and which meets the required criteria
b. At least two consumer/patient representatives
c. A representative from a Government health department
d. A representative from PFIH
e. A representative from the education sector
f. A representative from the finance sector
g. Secretariat provided by PFIH

<u>Recommendation 6</u>: **The work of the Working Group should be project managed by The Prince's Foundation for Integrated Health.**

In order to meet a very challenging time schedule, the work of the working group will need to be effectively and efficiently project managed. Given that PFIH are already committed to supporting the regulation of complementary healthcare, it would be logical that they continue with this on-going work.

<u>Recommendation 7:</u> The Working Group should be chaired by an Independent Chair, who is not associated with the bodies wishing to be part of the federal structure.

Given the challenging and potentially contentious nature of the detailed discussions to be held, the Independent Chair should not be associated with the aspirant federal professions. It will need to be someone with both a broad understanding of the regulation of complementary healthcare and the overall regulation scene.

<u>Recommendation 8:</u> The Working Group should be tasked as follows, to:

1) explore in detail the preferred model for a federal structure – concentrating on Approaches 4 and 5, as set out above
2) taking into account:
   I. the results of the consultation
   II. the contents of the Feasibility/Implementation study
   III. the implications of the reports on non-medical and medical regulation
   IV. the on-going work of the Joint WG for Herbal Medicine and Acupuncture and associated government proposals
3) make proposals for a model which is acceptable to all parties in the debate
4) identify a comprehensive communications strategy for public and professions
5) make proposals for an implementation timetable
6) make proposals for transitional arrangements
7) seek Governmental views on its proposals
8) prepare a report on its findings
9) consider whether further consultation is required and, if so, in what form

A challenging but possible time-table might be:

<u>By December 2006</u>

1. Commitment from the professions who meet the criteria set out in Recommendation 2 above and who wish to engage further in this work.
2. Working Group membership agreed
3. Working Group dates agreed for 2007

<u>January 2007</u>

First Working Group meeting and then monthly

<u>By end February March 2007</u>

Ball-park figures on identified costs for possible models

<u>September 2007</u>

Fuller cost and benefit analysis completed

<u>End September 2007</u>

Initial proposals on way forward, including transitional arrangements and future funding arrangements, from Working Group.

Recommendation 9: Start up costs should be identified as a matter of urgency by PFIH and the professions working towards a federal model.

PFIH, in conjunction with the professions participating in this work, will need to identify what funding can be provided for supporting the working group during the next phase of this work. Identification of on-going funding will also need to be undertaken. It is anticipated that the public protection agenda of this work would result in tangible and explicit governmental support.

Recommendation 10: A cost and benefit analysis of the preferred model(s) should be commissioned as soon as practicable.

One of the major concerns of many of the respondents to the consultation is the cost of any potential federal system. Once a particular approach/ model is agreed by the Working Group, then it should be formally costed without delay, in order to inform eventual proposals regarding the finances of the new 'body'. The body will have to be self-funding within an agreed period of time.

Conclusion

54. This report has ranged widely across the field of professional regulation – both in terms of the current context and also possible future changes. It has attempted to apply identified principles and practice to proposals for the future, whilst bearing in mind that the regulation of complementary therapies does not need to slavishly follow that of its statutory counterparts. It has incorporated the response to the consultation, taking into account the views of the many practitioners who responded. It has also taken cognizance of the proposals in the recent reports on non-medical and medical regulation.

55. Given that the consultation provided considerable support for the proposal for the establishment of a federal body, it now remains to move on with the work. The challenges of the next stage - gathering together a working group and tasking them to identify a definitive model with associated timetable which is acceptable to the profession concerned, should not be underestimated, both in terms of time and the challenge of reaching broad agreement amongst those concerned.

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